



DOCKET NO.: C1039.70073US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE


Applicant: Arthur M. Krieg et al.  
Serial No.: 10/743,625  
Confirmation No.: Not yet assigned  
Filed: December 22, 2003  
For: IMMUNOSTIMULATORY NUCLEIC ACID  
MOLECULES

Examiner: Not yet assigned  
Art Unit: Not yet assigned

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first/class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 8 day of March, 2004.

  
Helen C. Lockhart, Ph.D., Reg. No. 39,248

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313/1450

**SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above/identified case. No fee or certification is required.

**Information Cited**

Applicants hereby make of record in the above/identified application the information listed on the attached form PTO/1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicants hereby make the following additional information of record in the above/identified application.

Applicants would like to bring to the Examiner's attention the following co/pending applications that may contain subject matter related to this application (copies enclosed except for C1039.70083US01-07 which are identical to C1039.70083US00 which is enclosed):

Docket Number	Serial Number	Filing Date	Inventor(s)
C1037.70016US00	09/009,634	1/20/98	Hutcherson et al.
C1037.70021US00	09/949,194	9/7/01	Peterson et al.
C1037.70025US00	10/017,995	12/14/01	Bratzler
C1037.70038US01	10/735,592	12/11/03	Krieg et al.
C1037.70041US00	10/613,749	7/3/03	Krieg
C1037.70042US00	10/613,524	7/3/03	Krieg
C1037.70043US00	10/613,739	7/3/03	Krieg
C1037.70044US00	10/613,716	7/3/03	Krieg
C1037.70045US00	10/613,228	7/3/03	Krieg
C1037.70046US00	10/445,247	6/5/03	Krieg
C1037.70048US00	10/644,052	8/19/03	Krieg et al.
C1037.70049US00	10/643,141	8/18/03	Hutcherson et al.
C1037.70051US00	10/666,733	9/19/03	Bratzler et al.
C1037.70052US00	10/668,050	9/22/03	Bratzler et al.
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C1039.70036US00	09/559,140	4/27/00	Noll et al.
C1039.70042US00	09/630,319	7/31/00	Krieg et al.
C1039.70044US00	09/672,126	9/27/00	Hartmann et al.
C1039.70048US00	09/818,918	3/27/01	Krieg et al.
C1039.70048US01	10/769,282	1/30/04	Krieg et al.
C1039.70052US00	09/888,326	6/22/01	Weiner et al.
C1039.70057US00	09/965,101	9/26/01	Davis et al.
C1039.70058US00	10/023,909	12/18/01	Davis et al.
C1039.70061US00	10/161,229	6/3/02	Krieg et al.
C1039.70062US00	10/187,489	7/2/02	Krieg et al.
C1039.70063US00	10/224,523	8/19/02	Krieg et al.
C1039.70065US00	10/272,502	10/15/02	Krieg et al.
C1039.70067US00	10/300,247	11/20/02	Davis et al.
C1039.70068US00	10/306,522	11/27/02	Krieg et al.
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C1039.70075US00	10/613,916	7/3/03	Krieg et al.
C1039.70077US00	10/619,279	7/14/03	Krieg
C1039.70078US00	10/627,331	7/25/03	Krieg et al.

Docket Number	Serial Number	Filing Date	Inventor(s)
C1039.70079US00	10/627,413	7/25/03	Krieg et al.
C1039.70082US00	10/631,676	7/30/03	Krieg et al.
C1039.70083US00	10/690,495	10/21/03	Krieg
C1039.70083US01	10/769,626	1/30/04	Krieg et al.
C1039.70083US02	TBD	2/26/04	Krieg et al.
C1039.70083US03	TBD	2/26/04	Krieg et al.
C1039.70083US04	TBD	2/26/04	Krieg et al.
C1039.70083US05	TBD	2/26/04	Krieg et al.
C1039.70083US06	TBD	2/26/04	Krieg et al.
C1039.70083US07	TBD	2/26/04	Krieg et al.
C1039.70084US00	10/649,584	8/25/03	Krieg et al.
C1040.70010US00	09/768,012	1/22/01	Davis et al.
C1041.70002US00	09/241,653	2/2/99	Wagner et al.
C1041.70005US00	09/355,254	7/23/99	Wagner et al.
C1041.70010US00	09/786,436	9/3/99	Wagner et al.
C1041.70016US00	09/954,987	9/17/01	Bauer et al.
C1041.70019US00	10/140,013	5/6/02	Schetter et al.
C1041.70029US00	10/212,133	8/1/02	Lipford et al.
C1041.70031US00	10/265,072	10/5/02	Lipford
C1041.70035US00	10/373,381	2/24/03	Wagner et al.
C1041.70037US00	10/407,952	4/4/03	Lipford et al.
C1041.70040US00	10/666,844	9/19/03	Lipford et al.

### REMARKS

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO/1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, Applicant make no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

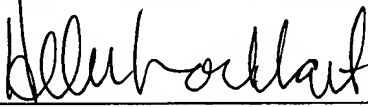
By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicants, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

*Arthur M. Krieg et al., Applicant*

By:   
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Docket No.: C1039.70073US00

Date: March 8, 2004

**xNDDx**

<b>FORM PTO/1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/743,625		ATTY. DOCKET NO.: C1039.70073US00	
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				GROUP ART UNIT: Not yet assigned		EXAMINER: Not yet assigned	
Sheet	3	of	4				

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials†	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM/DD/YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B1	WO	98/16247	A1	The Regents of the University of CA	04/23/1998	
	*	WO	98/32462	A1		07/30/1998	
	B2	WO	98/55495	A2	Dynavax Technologies Corporation	12/10/1998	
	B3	WO	99/11275	A2	The Regents of the University of CA	03/11/1999	
	*	WO	99/56755	A1		11/11/1999	
	*	WO	99/58118	A2		11/18/1999	
	B4	WO	99/62923	A2	Dynavax Technologies Corporation	12/09/1999	
	*	WO	00/06588	A1		02/10/2000	
	*	WO	00/14217	A3		03/16/2000	
	B5	WO	00/20039	A1	The Regents of the University of CA	04/13/2000	
	B6	WO	00/62787	A1	The Regents of the University of CA	10/26/2000	
	*	WO	00/67023	A1		11/09/2000	
	*	WO	01/22990	A2		04/05/2001	
	*	WO	02/69369	A2		09/06/2002	
	B7	WO	98/37919	A1	University of Iowa Research Foundation	09/03/1998	
	B8	WO	98/55609	A1	The Regents of the University of CA	12/10/1998	
	B9	WO	00/16804	A1	Dynavax Technologies Corporation	03/30/2000	
	B10	WO	01/02007	A1	The Regents of the University of CA	01/11/2001	
	B11	WO	01/68116	A2	Dynavax Technologies Corporation	09/20/2001	
	B12	WO	01/12223	A2	Dynavax Technologies Corporation	02/22/2001	
	B13	WO	99/11275	A2	The Regents of the University of CA	03/11/1999	
	B14	WO	96/40162	A1	East Carolina University	12/19/1996	
	B15	WO	98/49288	A1	Hybridon, Inc.	11/05/1998	

		OTHER ART – NON PATENT LITERATURE DOCUMENTS		
Examiner's Initials†	Cite No.	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume/issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	C1	AGRAWAL et al., Molecular med. <i>Today</i> , 6:72-81, 2000.		
	C2	ANDERSON, G. et al., "TH2 and TH2-like cells in allergy and asthma: pharmacological perspectives," <i>TiPS</i> , 15:324-332, 1994).		
	C3	BROIDE, D. et al., "DNA-Based Immunization for Asthma", <i>International Archives of Allergy and Immunology</i> , 1999, Pages 453-456, Vol. 118, S. Karger AG. Basel		
	C4	CROFT, M. et al., "Generation of Polarized Antigen-specific CD8 Effector Populations: Reciprocal Action of Interleukin (IL)-4 and IL-12 in Promoting Type 2 versus Type 1 Cytokine Profiles", <i>J. Exp. Med.</i> , November 1994, Pages 1715-1728, Vol. 180, The Rockefeller University Press		
	C5	HUANG, L.Y. et al., "Induction and Regulation of Th1-Inducing Cytokines by Bacterial DNA, Lipopolysaccharide, and Heat-Inactivated Bacteria", <i>Infection and Immunity</i> , December 1999, Pages 6257-6263, Vol. 67, No. 12, American Society for Microbiology		
	C6	KAWANO, K. et al., "Analysis and regulation of interferon-gamma production by peripheral blood lymphocytes from patients with bronchial asthma," <i>Arerugi</i> , 43:3:482-91, 1994 (Abstract).		
	C7	KLINE, J.N. et al., "CpG oligodeoxynucleotides do not require T <sub>H1</sub> cytokines to prevent eosinophilic airway inflammation in a murine model of asthma", <i>J. Allergy Clin. Immunol.</i> , December 1999, Pages 1258-1264, Vol. 104, No. 6		

<b>FORM PTO/1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		APPLICATION NO.: 10/743,625		ATTY. DOCKET NO.: C1039.70073US00	
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		GROUP ART UNIT: Not yet assigned		EXAMINER: Not yet assigned	
Sheet	4	of	4		

OTHER ART – NON PATENT LITERATURE DOCUMENTS					
Examiner's Initials†	Cite No.	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume/issue number(s), publisher, city and/or country where published.			Translation (Y/N)
	C8	KLINMAN, D.M., et al., "Activation of the innate immune system by CpG oligodeoxynucleotides: immunoprotective activity and safety," <i>Springer Semin Immunopathol</i> 22:173-183, 2000			
	C9	KRIEG, A.M., "An innate immune defense mechanism based on the recognition of CpG motifs in microbial DNA," <i>J Lab Clin Med</i> 128(2):128/33, 1996 (Abstract).			
	C10	KRIEG, A.M., et al., "CpG motifs in bacterial DNA and their immune effect." <i>Annu Rev Immunol</i> 20:709-760, 2002.			
	C11	KRIEG et al., <i>Immunology Today</i> 21(10):521-526, 2000.			
	C12	KRIEG, A.M. et al., "Immune effects and therapeutic applications of CpG motifs in bacterial DNA", <i>Immunopharmacology</i> , 2000, Pages 303-305, Vol. 48, Elsevier Science B.V.			
	C13	LIPFORD, G.B. et al., "Bacterial DNA as immune cell activator", <i>Trends Microbiol.</i> , 1998, Pages 496-500, Vol. 6, No. 12, Elsevier Science			
	C14	LIPFORD, G.B. et al., "Immunostimulatory DNA: sequence-dependent production of potentially harmful or useful cytokines," <i>Eur J Immunol</i> 27:3420-3426, 1997.			
	C15	MCCLUSKIE et al., <i>Molecular Med</i> 5(5):287-300, 1999.			
	C16	RICCI, M. et al., "T cells, cytokines, IgE and allergic airways inflammation," <i>J Invest Allergol Clin Immunol</i> , 4(5):214-220, 1994.			
	C17	SPIEGELBERG, H. et al., "Recognition of T Cell Epitopes and Lymphokine Secretion by Rye Grass Allergen <i>Lolium perenne</i> I-specific Human T Cell Clones," <i>J of Immunology</i> , 4706-4711, 1994.			
	C18	VAN UDEN, J. et al., "Immunostimulatory DNA and applications to allergic disease", <i>J. Allergy Clin. Immunol.</i> , November 1999, Pages 902-910, Vol. 104, No. 5			
	C19	WALKER, C. et al., "Activated T Cells and cytokines in bronchoalveolar lavages from patients with various lung diseases associated with eosinophilia," <i>Am J Respir Crit Care Med</i> , 150:1038-1048, 1994.			
	C20	ZIMMERMANN, S. et al., "CpG oligodeoxynucleotides trigger protective and curative Th1 responses in lethal murine leishmaniasis," <i>J Immunol</i> 160:3627/3630, 1998.			

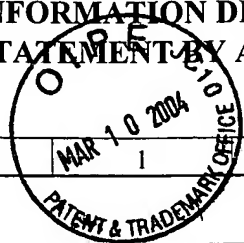
EXAMINER	DATE CONSIDERED
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†EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 09/818,918 or Serial No. 08/738,652, filed on October 30, 1996 and now issued as U.S. Patent No. 6,207,646, issued on March 27, 2001, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in/part, and divisional applications).

\*\* copies of these patents and patent applications are not enclosed pursuant to the waiver by the USPTO of the requirement under 37 C.F.R. 1.98 (a)(2)(i) for patent applications filed after June 30, 2003.

FORM PTO/1449/A and B (Modified)		APPLICATION NO.: 10/743,625	ATTY. DOCKET NO.: C1039.70073US00
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Sheet 1 of 4			



### U.S. DOCUMENTS

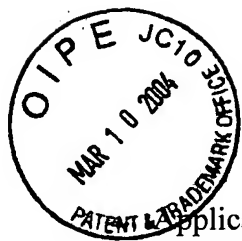
Examiner's Initials†	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM/DD/YYYY
		Number	Kind Code		
	**	5,679,647		Carson et al.	10/21/1997
	**	5,994,315		Nyce et al.	11/30/1999
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	**	6,174,872	B1	Carson et al.	01/16/2001
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	**	US 2002/0107212	A1	Van Nest et al.	08/08/2002
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	**	US 2002/0156033	A1	Bratzler et al.	10/24/2002
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	**	US 2003/0078223	A1	Raz et al.	04/24/2003
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<b>FORM PTO/1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/743,625		ATTY. DOCKET NO.: C1039.70073US00			
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Sheet	2	of	4						

**U.S. DOCUMENTS (cont.)**

Examiner's Initials†	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM/DD/YYYY
	**	US 2003/0216340	A1	Van Nest et al.	11/20/2003
	**	US 2001/0046967	A1	Van Nest	11/29/2001
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	**	US 2002/0198165	A1	Bratzler et al.	12/26/2002
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	**	US 2003/0191079	A1	Krieg et al.	10/09/2003
	**	US 2003/0225016	A1	Fearon et al.	10/23/2003
	**	US 2004/0006610	A1	Carson et al.	10/23/2003





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MOLECULES

Examiner: Not yet assigned  
Art Unit: Not yet assigned

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on March 8, 2004.

  
Helen C. Lockhart

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL**

Sir:

Transmitted herewith is/are the following document(s):

- ☒ Supplemental Information Disclosure Statement;
- ☒ PTO Form 1449 (copies of references cited);
- ☒ Return Receipt Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

No fee is enclosed. If there is a fee, please charge to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully Submitted,



Helen C. Lockhart; Reg. No. 39,248  
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Date: March 8, 2004  
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